IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO

JOSE JIMENEZ	§	
Plaintiff,	§	
	§	
vs.	§	**CASE NO. 1:09-cv-00416 MCA DJS**
	§	
SMITH & NEPHEW, INC.	§	
Defendants.	§	

PLAINTIFF JOSE JIMENEZ'S
DESIGNATION OF EXPERTS

COME NOW, JOSE JIMENEZ, Plaintiffs herein, by and through their undersigned attorneys, making their designation of experts, pursuant to the Court's Scheduling Order and Fed. R. Civ. P 26(a)(2).

The following experts may be used by Plaintiff at time of trial to present evidence under Federal Rule of Evidence 702, 703 or 705:

P. Edward Purdue, PhD
Osteolysis Research Laboratory
& Researchers,
Biomechanical Research
Hospital for Special Surgery
535 E. 70th Street
New York, NY 10021
Phone 212-606-1437
Email purduee@hss.edu

Dr. Purdue and the research team at the Hospital for Special Surgery have specialized knowledge regarding the effect of prosthetic wear debris in periprosthetic osteolysis. They will testify as to their examination of the subject implant and their findings, as well as their expert opinions as to the cause of failure of Mr. Wehner's prosthetic device. Dr. Purdue's CV, fee schedule, relevant articles, list of publications and report of opinion is attached.

Ronald R. Hugate, Jr., MD
Colorado Limb Consultants

1601 E. 19th Avenue, Suite 3300
Denver, Colorado 80218
Phone (303) 837-0072
Hugate@msn.com

Dr. Hugate is a board certified orthopedic surgeon, a member physician of the Denver Clinic for Extremities at Risk, Presbyterian/St. Luke's Medical Center. He will testify as to his examination of the subject implant and his findings, as well as his expert opinion as to the cause of the failure of Mr. Wehner's prosthetic device. Dr. Hugate's CV, fee schedule, list of publications and report of opinion is attached.

Respectfully submitted,
HOUSSIERE, DURANT & HOUSSIERE, LLP

By: /S/
Julie Mayes Hamrick
Texas State Bar No. 08878420
1990 Post Oak Blvd., Suite 800
Houston, Texas 77056-3812
Tel:(713)626-3700
Fax:(713)626-3709
Jhamrick@hdhtex.com
ATTORNEYS FOR PLAINTIFF, *pro hac vice*

CERTIFICATE OF SERVICE

This will certify that a true and correct copy of *Plaintiff 's Designation of Experts* has been forwarded to all counsel of record as addressed below, by the court's electronic service, certified mail, return receipt requested, and/or facsimile transmission and/or regular U.S. mail and/or hand delivery on the 15th day of January, 2010 to:

Stephen Portell
Harrison, Miller, Pitt,
Feldman & McAnaly, PLC
One S. Church St. #900
Tucson, AZ 85701
Telephone 520-792-3836
Fax 520-624-5080

James W. Klipstine, Jr.
1601 N. Turner #400
Hobbs, NM 88240
Tel: (575) 393-1300
Fax: (575) 393-1869
jklipstine @windstream.net

Thomas Outler
Rodey, Dickason, Sloan,
Akin & Robb, PA
P.O. Box 1888
Albuquerque, NM 87103
Telephone 505-768-7256
Fax 505-768-7395

/S/
JULIE MAYES HAMRICK

PAUL EDWARD PURDUE
1180 Sussex Road
Teaneck, NJ 07666
email: purduee@hss.edu

Work Experience

2004-present **Associate Scientist and Director of Laboratory of Osteolysis Research, Hospital for Special Surgery, New York, NY**

1992-2004 **Mount Sinai School of Medicine, Dept. of Cell Biology/Anatomy, New York, NY.**
1995-2004 **Assistant Professor**
1992-1995 **Postdoctoral Fellow**

1988-1992 **Non-Clinical Postdoctoral Scientist, MRC Clinical Research Centre, London, U.K.**

Education

1988 PhD, Edinburgh University, Scotland.
1984 BA (double first class honors), Natural Sciences, Cambridge University, England.

Related Professional Experience and Awards

2008 Recipient of Hospital for Special Surgery Fellowship in Arthroplasty

2000-present Member, Medical and Scientific Advisory Board, The Oxalosis and Hyperoxaluria Foundation (OHF)

Publications

Original Peer-Reviewed Reports

1. Purdue, P.E., Y. Takada and C.J. Danpure, Identification of mutations associated with peroxisome-to-mitochondrion mistargeting of alanine:glyoxylate aminotransferase in primary hyperoxaluria type 1. J.Cell Biol. 111: 2341-2351 (1990)
2. Danpure, C.J., K.M. Guttridge, P. Fryer, P.R. Jennings and P.E. Purdue. Subcellular distribution of hepatic alanine:glyoxylate aminotransferase in various mammalian species. J.Cell Sci. 97: 669-678 (1990)
3. Takada, Y., N. Kaneko, H. Esumi, P.E. Purdue and C.J. Danpure. Human peroxisomal L-alanine:glyoxylate aminotransferase. Evolutionary loss of a mitochondrial targeting sequence by point mutation of the initiation codon. Biochem J. 268: 517-520 (1990)
4. Winning, B.M., B. Bathgate, P.E. Purdue and C.J. Leaver. Nucleotide sequence of a full-length cDNA encoding the beta subunit of the mitochondrial ATPase from Zea mays. Nucleic Acids Res. 18: 5885 (1990)
5. Purdue, P.E., M.J. Lumb, M. Fox, G. Griffo, C. Hamon-Benais, S. Povey and C.J. Danpure. Characterization and chromosomal mapping of a genomic clone encoding human alanine:glyoxylate aminotransferase. Genomics 10: 34-42 (1991)
6. Purdue, P.E., M.J. Lumb, J. Allsop and C.J. Danpure. An intronic duplication in the alanine:glyoxylate aminotransferase gene facilitates identification of mutations in compound heterozygotes with primary hyperoxaluria type 1. Hum. Genet. 87: 394-396 (1991)
7. Purdue, P.E., J. Allsop, G. Isaya, L.E. Rosenberg and C.J. Danpure. Mistargeting to mitochondria of alanine:glyoxylate aminotransferase in primary hyperoxaluria patients; activation of a cryptic mitochondrial targeting sequence by a point mutation. Proc. Natl. Acad. Sci. (USA) 88: 10900-10904 (1991)
8. Purdue, P.E., M.J. Lumb, J. Allsop, Y. Minatogawa and C.J. Danpure. A glycine-to-glutamate substitution abolishes alanine:glyoxylate aminotransferase catalytic activity in a subset of patients with primary hyperoxaluria type 1. Genomics 13: 215-218 (1992)
9. Purdue, P.E., M.J. Lumb and C.J. Danpure. Molecular evolution of alanine:glyoxylate aminotransferase intracellular targeting. Analysis of the marmoset and rabbit genes. Eur.J.Biochem. 207: 757-766 (1992)
10. Winning, B.M., C.J. Sarah, P.E. Purdue, C.D. Day and C.J. Leaver. The adenine nucleotide translocator of higher plants is synthesized as a large precursor that is processed upon import into mitochondria. The Plant Journal 2: 763-773 (1992)
11. Minatogawa, Y., S. Tone, J. Allsop, P.E. Purdue, Y. Takada, C.J. Danpure and R. Kido. A serine-to-phenylalanine substitution leads to loss of alanine:glyoxylate aminotransferase catalytic activity and immunoreactivity in a patient with primary hyperoxaluria type 1. Hum. Mol. Genet. 1: 643-644 (1992)
12. Danpure, C.J., P.E. Purdue, P, Fryer, S. Griffiths, J. Allsop, M.J. Lumb, K.M. Guttridge, P.R. Jennings, J.I. Scheinman, S.M. Mauer and N.O. Davidson. Enzymological and mutational analysis of a complex primary hyperoxaluria type 1 phenotype involving alanine:glyoxylate aminotransferase peroxisome to mitochondrion mistargeting and intraperoxisomal aggregation. Am.J.Hum.Genet. 53: 417-432 (1993)
13. Lumb, M.J., P.E. Purdue and C.J. Danpure. Molecular evolution of alanine/glyoxylate aminotransferase intracellular targeting. Analysis of the feline gene. Eur.J.Biochem. 221: 53-62 (1994)
14. Danpure, C.J., G.M. Birdsey, G. Rumsby, M.J. Lumb, P.E. Purdue and J. Allsop. Molecular characterization and clinical use of a polymorphic tandem repeat in an intron of the human alanine:glyoxylate aminotransferase gene. Hum. Genet. 94: 55-64 (1994)
15. Danpure, C.J., P.R. Jennings, P. Fryer, P.E. Purdue and J. Allsop. Primary hyperoxaluria type 1: Genetic and phenotypic heterogeneity. J. Inher. Metab. Dis. 17: 487-499 (1994)
16. Purdue, P.E. and P.B. Lazarow. Peroxisome biogenesis. Multiple pathways of protein import. J.Biol.Chem. 269: 30065-30068 (1994)
17. Purdue, P.E. and P.B. Lazarow. Identification of peroxisomal membrane ghosts with an epitope-tagged integral membrane protein in yeast mutants lacking peroxisomes. Yeast, 11: 1045-1060 (1995)
18. Purdue, P.E. and P.B. Lazarow. Targeting of human catalase to peroxisomes is dependent upon a novel C-terminal peroxisomal targeting sequence. J. Cell Biol, 134: 849-862 (1996)

19. Lazarow, P.B., X. Cai, S.M. Castro, V. Protopropov, P.E. Purdue and J. Zhang. A branched pathway of peroxisomal protein import. Ann. N.Y. Acad. Sci., 804: 21-33 (1996)
20. Purdue, P.E., J. Zhang, M. Skoneczny and P.B. Lazarow. Rhizomelic chondrodysplasia punctata is caused by deficiency of human Pex7p, a homologue of the yeast PTS2 receptor. Nature Genetics, 15: 381-384 (1997)
21. Nagan, N., H. Moser, P.E. Purdue, P.B. Lazarow and R.A. Zoeller. A fibroblast cell line defective in alkyl-DHAP synthase: A novel defect in plasmalogen biosynthesis. Proc. Natl. Acad. Sci. (USA), 94: 4475-4480 (1997)
22. Nagan, N., A.K. Hajra, L.K. Larkins, P.B. Lazarow, P.E. Purdue, W.B. Rizzo and R.A. Zoeller. Isolation of a chinese hamster fibroblast variant defective in dihydroxyacetonephosphate acyltransferase activity and plasmalogen biosythesis: Use of a novel two-step selection protocol. Biochem. J 332: 273-279 (1998)
23. Purdue, P.E., X. Yang and P.B. Lazarow. Pex18p and Pex21p, a novel pair of related peroxins essential for targeting by the PTS2 pathway. J. Cell Biol. 143: 1859-1869 (1998)
24. Purdue, P.E., M. Skoneczny, X. Yang, J. Zhang and P.B. Lazarow. Rhizomelic chondrodysplasia punctata, a peroxisomal biogenesis disorder caused by defects in PEX7, a peroxisomal protein import receptor. Neurochemical Research 24: 571-576 (1999)
25. Knott, T.G., G.M. Birdsey, K.E. Sinclair, I.M. Gallagher, P.E. Purdue and C.J. Danpure. The PTS1 receptor Pex5p and the peroxisomal import efficiency of alanine:glyoxylate aminotransferase. Biochem. J. 352: 409-418 (2000)
26. Yang, X., P.E. Purdue and P.B. Lazarow Eci1p uses a PTS1 to enter peroxisomes; either its own, or that of a partner, Dci1p. Eur. J. Cell Biol. 80: 126-138 (2001)
27. Purdue, P.E. and P.B. Lazarow. 2001. Peroxisomes (human) *in* Encyclopedia of Molecular Medicine. (New York: John Wiley & Sons) *4*:2450-2453.
28. Purdue, P.E. and P.B. Lazarow. 2001. Peroxisome Biogenesis. Ann. Rev. Cell Dev. Biol., *17*:701-52.
29. Purdue, P.E. And P.B. Lazarow Pex18p is constitutively degraded during peroxisome biogenesis. J. Biol. Chem. 276:47684-47689 (2001)
30. Sato, M., S. Tone, T. Ishikawa, P.E. Purdue, C.J. Danpure and Y. Minatogawa. Functional analysis of the 5′-flanking region of the human alanine:glyoxylate aminotransferase gene *AGXT* Biochim. Biophys Acta (Gene Structure and Expression) 1574(2):205-9 (2002)
31. Nair, D.M., P.E.Purdue and P.B.Lazarow. Pex7p translocates in and out of peroxisomes in *Saccharomyces cerevisiae*. J. Cell Biol. 167: 599-604 (2004).
32. Rakshit, DS., K. Ly, TK Sengupta, BJ Nestor, TP Sculco, LB Ivashkiv and PE Purdue. Wear debris inhibition of anti-osteoclastogenic signaling by interleukin-6 and interferon-gamma. Mechanistic insights and implications for periprosthetic osteolysis. J Bone Joint Surg Am. 2006 Apr;88 (4):788-99.
33. Rakshit DS, Lim JTE, Ly K, Ivashkiv LB, Nestor BJ, Sculco TP, Purdue PE: Involvement of complement receptor 3 (CR3) and scavenger receptor in macrophage responses to wear debris. J. Orthopaedic Research 2006 24(11):2036-2044.
34. Purdue PE, Koulouvaris P, Nestor BJ and Sculco TP. The Central Role of Wear Debris in Periprosthetic Osteolysis. journal@hss 2006 2:102-113.
35. Purdue PE, Koulouvaris P, Potter HG, Nestor BJ and Sculco TP. The cellular and molecular biology of periprosthetic osteolysis. Clinical Orthopaedics and Related Research 2007 454:251-261
36. Koulouvaris P, Ly K, Ivashkiv LB, Bostrom MP, Nestor BJ, and Sculco TP. Expression profiling reveals alternative macrophage activation and impaired osteogenesis in periprosthetic osteolysis. J. Orthopaedic Research 2008 26(1):106-116.
37. Purdue PE. Alternative macrophage activation in periprosthetic osteolysis. Autoimmunity 2008 41:3, 212 - 217

Books

36. Danpure, C.J. and P.E. Purdue. Primary hyperoxaluria. In "The Metabolic and Molecular Bases of Inherited Disease" (7th Edition), McGraw-Hill, Eds. Scriver, C.R., Beaudet, A.L., Sly, W.S. and Valle, D., pp 2385-2424 (1995)

Invited Contributions

37. Purdue, P.E. and P.B. Lazarow. Peroxisomes. In "The Encyclopedia of Molecular Medicine" (1st Edition), John Wiley and Sons, New York, Ed, T.E. Creighton, Vol 4, pp 2450-2453 (2001)

38. Purdue, P.E. and P.B. Lazarow. Peroxisome Biogenesis. Annual Review of Cell and Developmental Biology 17: 701-752 (2001)

Julie Hamrick

From: Purdue, Ed PhD [PurdueE@HSS.EDU]
Sent: Friday, January 15, 2010 1:09 PM
To: Julie Hamrick
Subject: Re:

Dear Ms. Hamrick,

My fee schedule for study and testimony in this case is $400/hour ($3200/day)

Yours,

P. Edward Purdue
Director, Osteolysis Research Laboratory Hospital for Special Surgery
535 East 70th Street
New York
NY 10021

On 1/15/10 2:07 PM, "Julie Hamrick" <Jhamrick@hdhtex.com> wrote:

Julie Mayes Hamrick

Attorney at Law

Houssiere, Durant & Houssiere, LLP

1990 Post Oak Boulevard, Suite 800

Houston, TX 77056

(713) 626-3700 office

(713) 626-3709 fax

Jhamrick@HDHtex.com

January 15, 2010

Julie Mayes Hamrick
HOUSSIERE, DURANT, HOUSSIERE, LLP
1990 Post Oak Boulevard, Suite 800
Houston, TX 77056

Re: Patient: Jose Jimenez

Dear Counsel:

This letter will provide a summary of my expert opinion as related to the complications of total knee arthroplasty experienced by this patient.

1. In forming my opinion, I have reviewed and considered the following, and may use any of the following as an exhibit should my testimony be required at trial:

   Patient's history, operative reports, discharge summaries and chartsticks for primary and revision total knee arthroplasty.

   Office record of patient's treating surgeons.

   Patient's Relevant Radiological and Pathological reports.

   Medical Articles, including:

   Purdue, Koulouvaris, Nestor, & Sculco *The Central Role of Wear Debris in Periprosthetic Osteolysis*, Journal@hss 2:102-113 (2006)

   Batista, Ibarra, Ortiz & Melvitz, *Engineering Biomechanics of Knee Replacement*, Applications of Engineering Mechanics in Medicine, May 2004

   Spector, *Biomaterials Survey*, MIT, Harvard Medical School, Brigham & Women's Hospital, VA Boston Healthcare System

2. I am qualified to provide this opinion, as represented by the qualifications presented on my curriculum vitae, attached hereto. I have conducted special research into the conclusions presented in this opinion. A list of all publications which I have authored in the past 10 years is attached to my curriculum vitae.

3. A list of all other cases in which, during the previous four years, I have testified as an expert at trial or by deposition is attached hereto.

4. A copy of my fee schedule, outlining the compensation to be paid for study and testimony in this case is attached hereto.

5. My opinions in this case, based upon my training, knowledge and expertise, along with the basis and reasons for them are as follows:

My background is limited to my education and research into mechanisms of bone loss. I have not performed any mechanical testing on the device used in this patient. The opinions expressed here are based upon my training and expertise, my knowledge as a result of my regular study of peer-reviewed journals and literature, including those listed above which provide specific explanation of my theories, as well as my review of the patient's records.

The commonly known causes of early loosening of prosthetic implants are failure to initially fixate with bony ingrowth, cement complications, prosthetic fracture, and infection. Therefore, when the standard causes are ruled out in a patient presenting with early loosening after appropriate testing, the next step is to consider osteolysis as the cause. Osteolysis is the major long-term complication of total knee arthroplasty. Significant osteolysis is frequently accompanied by loosening. Therefore, early osteolysis should be considered in a patient suffering early loosening with none of the common causes. Osteolysis may be difficult to detect on radiographs or routine surveillance.

Osteolysis occurs when wear debris from a joint prosthesis becomes engulfed by macrophages, causing activation of pro-inflammatory signaling, leading to increased osteoclast recruitment and activation. This debris may originate from articulation wear upon any portion of the device and/or from bone cement. Macrophages are innate immune cells responsible for removing foreign particles from the body. After engulfing prosthetic wear particles, they activate MAP kinase cascades, NfkB proteins and other transcription factors leading to production of pro-inflammatory cytokines. Smaller wear particles are more inflammatory to macrophages. Released pro-inflammatory cytokines cause recruitment and activation of osteoclasts. Osteoclasts are the cells responsible for bone resorption (bone destruction). When these events occur in the vicinity of bone, the increased osteoclast activity leads to pathological bone loss (osteolysis) that, in turn, can cause loosening of the prosthesis.

Smith and Nephew has trademarked the *Oxinium* technology in prosthetic manufacture. This technology is marketed as "longer lasting" because the patented process of "transforming the surface" of a zirconium metal implant to ceramic results in a superior bearing surface, resisting abrasion to minimize generation of wear particles.

Strategies to reduce osteolysis by choosing bearing surface materials with reduced wear should be balanced by an awareness that reducing the size of wear particles may increase biologic activity, resulting in a more intense inflammatory reaction. Although clinical trials confirm that *Oxinium* technology results in a lower wear rate, there is no clinical data which indicates that the technology will reduce osteolysis. This demonstrates a failure of the manufacturer to consider the potential for a more severe reaction to the smaller wear particles.

The chartsticks found in patient Jose Jimenez's record indicates his index left knee implant was the *Oxinium* model. Mr. Jimenez's record indicates no infection or mechanical failure of his left knee implant. Pre-operative radiology reports indicated osteolysis involving the tibial component suggestive for loosening. This indicates early osteolysis in Mr. Jimenez's joint, likely resulting from wear particles. It is my opinion that wear debris-induced osteolysis likely contributed to the early failure of this patient's total knee arthroplasty.

The opinion presented herein may be supported with other evidence determined throughout the discovery process at a later date in this case. If testing of the subject device is an option, it may be possible to further explain the physiology of the loosening. However, based upon the facts presented above, it is my expert opinion that in all reasonable medical probability, this patient suffered loosening as a result of osteolysis caused by wear debris of the product used.

Sincerely,

P. Edward Purdue, PhD

Attachments:

Medical Articles

Ronald R. Hugate, MD

Dr. Hugate relocated to Denver after completing a fellowship in orthopedic oncology at the Mayo Clinic in Rochester, Minnesota. He specializes in complex joint replacement and bone and soft tissue tumors. His internship and residency were done at Penn State University after graduating with honors from Eastern Virginia Medical School. As a Major in the U.S. Army Reserves Medical Corps, he was awarded the Army Commendation Medal for his service at the Combat Surgical Hospital in Baghdad. He is the most recent addition to The Denver Clinic team, having joined in 2005. For Dr. Hugate's full CV, which is printable, please click here.

CURRICULUM VITAE

Board Certified Orthopedic Surgeon
Colorado Limb Consultants
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Denver, Colorado 80218
(303) 837-0072 / FAX (303) 837-0075

Member Physician
The Denver Clinic for Extremities at Risk
Presbyterian/St. Luke's Medical Center
Denver, Colorado

Education
Bachelor of Science 1994 Mechanical Engineering (*magna cum laude*)
Virginia Polytechnic Institute and State University, Blacksburg, VA

Medical Doctor 1998 Doctor of Medicine
Eastern Virginia Medical School, Norfolk, VA

Internship 1998-99 Surgical Internship
Milton S. Hershey Medical Center, Pennsylvania State University College of Medicine, Hershey, PA

Residency 1999-2003 Orthopedic Surgery
Department of Orthopaedics & Rehabilitation, Pennsylvania State University College of Medicine, Hershey, PA

Fellowship 2003-2004 Ivins Research Fellow
The Mayo Clinic, Rochester, MI
2004-2005 Orthopaedic Oncology Fellowship
The Mayo Clinic, Rochester, MI

Academic Rank 2005 Instructor of Orthopaedics

The Mayo Clinic, Rochester, MI

Military Service
United States Army Reserve, Medical Corps
5502nd U.S. Army Hospital. Denver, Colorado. July 1998 to present
Rank: Major
AMEDD Officer Basic Course completed September 1995
Operation Iraqi Freedom/Enduring Freedom:
- Deployed Aug – Dec 2003 to Baghdad, Iraq (28th combat surgical hospital)
- Deployed May - August 2005 Tripler Army Medical Center
- Deployed April - July 2008 Tripler Army Medical Center

Virginia Army Reserve/ National Guard
Medical Service Corps. Virginia Beach, VA. March 1994 –June 1998
Rank: First Lieutenant

Medical Licensure
State of Colorado (43557) issued 5/2005, currently active
State of Minnesota (45737) issued 5/2003, expired 4/2006
State of Pennsylvania (MD072910L) issued 2/2001, expired 12/2004

Selected Honors and Awards
Army Commendation Medal, December 2003
Awarded by the U.S. Army for service as an orthopaedic surgeon in support of Operation Iraqi Freedom. 28th Combat Surgical Hospital. Baghdad, Iraq.
Eastern Virginia Medical School, August 1994 - May 1998
Honors in Internal Medicine, Family Medicine, Obstetrics/Gynecology, Surgery, Orthopaedic Trauma, Reconstructive Orthopaedics
Virginia Polytechnic Institute and State University
Dean's List every semester attended
Graduated magna cum laude (May 1994)

Professional Certifications
American Board of Orthopedic Surgery (ABOS) July 2007-Present
AO/ASIF Principles of Fracture Management Course for Residents, Charleston SC, 2001

Professional Affiliations
The Ivins Society (Mayo Clinic Orthopaedic Oncology Fellows). 2005 – present
The Society of Military Orthopedic Surgeons (SOMOS). 2000 – present
The Denver Clinic for Extremities at Risk. 2005 – present
The Mayo Fellows' Association, 2003 – present
The American Academy of Orthopedic Surgeons, 1998 - present The American Medical Association, 1994-present
The Pennsylvania Orthopaedic Society, 1998-2003
The American College of Emergency Physicians, 1996-1998
The American Society of Mechanical Engineers, 1992-1994

Current Administrative Positions Held
Physician Member
The Denver Clinic for Extremities at Risk
Denver, Colorado
2007 – Present
Vice-Chairman, Department of Orthopedics
Presbyterian/St. Luke's Medical Center
Denver, Colorado
2008-2009
Inaugural Governing Board Member

The Colorado Orthopedic and Surgical Hospital
Denver, Colorado
2007 - Present
Medical Director
Parker Hospital Joint Replacement Program
Parker, Colorado
2007 - Present
Guest Editor
Clinical Orthopedics and Related Research
2005-Present

Clinical Consulting
Clinical Consultant
Stryker Corporation (Mahwah, New Jersey)
Design/Development of canine osseous integration implants for use in trans-radial amputees
2006-2007
Clinical Consultant
Wright Medical Corporation (Memphis, Tennessee)
Design/Development of implants which utilize foam metal technologies as an in-growth medium
2007-present

Research Interests
Advancement of bio-integrated implants
Orthopedic implant design
Medical and surgical treatment of osteogenic sarcoma
Pelvic/Sacral reconstruction

Research Funding
-Fixed angle Screws versus Standard Screws in Hemispherical Acetabular Fixation: A Biomechanical Study. Mayo Clinic Orthopaedic Research Grant. May 2004.

-The Biomechanical Consequences of Partial Transverse Sacrectomy: When is Reconstruction Necessary? Mayo Clinic Orthopaedic research grant. May 2004.

-Allograft Prosthetic Composite Reconstruction of the Proximal Tibia versus Proximal Tibial Reconstruction with Endoprosthesis: A Pilot Study to Define the Key Variables of Quadriceps Strength and Function. Mayo Clinic Department of Orthopaedic Surgery, Musculoskeletal Tumor Foundation Grant, January 2004.

-The Effects of Intratendinous and Peritendinous Corticosteroid Injections on the Biomechanical Properties of Rabbit Achilles Tendon. Pennsylvania State University College of Medicine Department of Orthopaedics and Rehabilitation, Orthopaedic Research Initiation Grant, July 2001.

-Design of an Automated Needle/Armature Tray Loader. Department of Mechanical Engineering, Virginia Polytechnic Institute and State University. Siemens Corporation Automotive Division Research Grant, September 1993.

Publications

1. Hugate RR; Dickey ID; Chen Q; Wood C; Rock MG; Sim FH: Locked Screws versus Standard Screws in Hemispherical Acetabular Fixation: A Biomechanical Study. [Final edit complete. Pending print in the Journal of Arthroplasty]
2. Hugate RR; Wilkins RM; Kelly CM; Madsen W; Hinshaw I; Camozzi AB: Intra-arterial Chemotherapy for Extremity Osteosarcoma and MFH in Adults. Clin Orthop Relat Res. 2008. Jun;466(6): 1292-301.
3. Drygus KA; Taylor RV; Sidebotham CG; Hugate RR; McAlexander H: Transcutaneous Tibial Implants: A Surgical Procedure for Restoring Ambulation after Amputation of the Distal Aspect of

the Tibia in a Dog. Vet Surg 37:322-327, 2008.

4. Damron TA; Leerapun T; Hugate RR; Shives TC; Sim FH: Does the Second Generation Intercalary Humeral Spacer Improve on the First? Clin Orthop Relat Res. 2008 Jun; 466(6):1309-17.
5. Leerapun T; Hugate RR; Inwards CY; Sculley SP; Sim FH: Surgical Management of Conventional Grade I Chondrosarcoma of Long bones. Clin Orthop Relat Res. 2007. Oct; 463: 166-72.
6. Pradhan A; Cheung YC; Grimer RJ; Abudu A; Peake D; Ferguson PC; Griffin AM; Wunder JS; O'sullivan B; Hugate RR; Sim FH: Does the Method of Treatment Effect the Outcome in Soft Tissue Sarcomas of the Adductor Compartment? J Bone Joint Surg Br. 2006 Nov; 88(11): 1480-6.
7. Hsu JT; Chang CH; An KN; Zobitz ME; Phimolsarnti R; Hugate RR; Lai KA: Effects of Screw Eccentricity on the Initial Stability of the Acetabular Cup. Int Orthop, Sept. 2006.
8. Hugate RR; Dickey ID; Phimolsamti R; Yaszemski M; Sim FH: Mechanical Effects of Partial Sacrectomy: When is Reconstruction Necessary? Clin Orthop Relat Res. 2006 450:82-8.
9. Hugate RR; O'Connor MI; Sim FH: Pelvic tumors. *In* Puri A, Agarwal MG (eds): Current Concepts in Bone and Soft Tissue Tumors [Chapter 18]. Arihant Book House, Parel, Mumbai, 2006, pp. 210-26.
10. Hugate RR; Sim FH: Pelvic reconstruction techniques. Orthop Clin North Am 37:85-99, 2006.
11. Dickey ID; Hugate RR; Fuchs B;Yaszemski M; Sim FH: Reconstruction After Total Sacrectomy: Early Experience with a New Surgical Technique. Clin Orthop Relat Res. 438:42-50, 2005.
12. Hugate RR; Sim F: Innovations in musculoskeletal oncology: 2004. J Orthop Sci.10:331-40, 2005.
13. Hugate RR; Pennypacker J; Saunders M; Juliano P: The Effects of Intratendinous and Retrocalcaneal Intrabursal Injections of Corticosteroid on the Biomechanical Properties of Rabbit Achilles Tendons. J Bone Joint Surg 86A:794-801, 2004.
14. Fayyazi AH; Hugate RR; Pennypacker J; Gelb DE; Ludwig SC: Accuracy of Computed Tomography in Assessing Thoracic Pedicle Screw Malposition. J Spinal Disord Tech 17:367-371, 2004.
15. Hugate RR; Sim FH; and Scully SP: Osseous Lesions of the Pre-Sacral Space. Sem Colon Rectal Surg 15: 41-54, 2004.
16. Hugate RR; Pellegrini VD Jr: Reactivation of Ancient Tuberculous Arthritis of the Hip Following Total Hip Arthroplasty: A Case Report. J Bone Joint Surg 84A:101-105, 2002.

Presentations

1. "Reconstructive Surgery for the Arm Amputee" Skills for Life Upper Extremity Limb Loss Workshop. Denver, Colorado October 10, 2008
2. "Advances in the Management of Shoulder Tumors" The Rocky Mountain Shoulder and Elbow Society. Boulder, Colorado. July 20, 2007.
3. "Foam Metal Materials" The Penn State Department of Orthopedics Grand Rounds. The Penn State College of Medicine. Hershey, Pennsylvania. August 2007.
4. "Management of Metastatic Lesions" Annual Colorado Trauma Symposium, Hyatt Regency Tech Center. Denver, Colorado. March 16, 2007.
5. "Prosthetic Infections" Annual Winter Conference, The Denver Clinic for Extremities at Risk. Presbyterian/St. Luke's Medical Center. Denver, Colorado. December 4, 2006.
6. "Fixed Angle Screws versus Standard Screws in Acetabular Prosthesis Fixation: A Cadaveric Biomechanical Study" The Annual Meeting of the Western Orthopaedic Association. Santa Fe, New Mexico. October 11, 2006.
7. "Management of Extremity Tumors: Avoiding Pitfalls" The Annual Winter Conference, The Denver Clinic for Extremities at Risk. Presbyterian/St. Luke's Medical Center. Denver, Colorado. December 2, 2005.
8. "The Biomechanical Consequences of Partial Transverse Sacrectomy: When is Reconstruction Necessary?" Musculoskeletal Tumor Society. Nashville, Tennessee. May 2005.
9. "The Biomechanical Consequences of Partial Transverse Sacrectomy: When is Reconstruction Necessary?" Canadian Orthopaedic Assoc. Montreal, Canada. June 2005.
10. "Surgical Management of Conventional Grade I Chondrosarcoma of Long Bones" American Academy of Orthopaedic Surgeons. Washington DC. February 2005.
11. "Soft Tissue Attachment to Highly-porous Alumina Ceramic Foams: An in vivo Canine" Orthopaedic Research Society. Washington DC. February 2005.
12. "Soft Tissue Attachment to Highly-porous Alumina Ceramic Foams: An in vivo Canine" Society for Biomaterials Annual Meeting. Memphis, Tennessee. April 2005.
13. "Soft Tissue Attachment to Highly-porous Alumina Ceramic Foams: An in vivo Canine Study" Canadian Orthopaedic Association. Montreal, Canada. June 2005.
14. "Biopsy Principles and Techniques" Saturday Morning Conference. Mayo Graduate School of

Medicine. Rochester,Minnesota. August 2004.

15. "Battlefield Orthopaedics" Hospital-wide Grand Rounds. Pennsylvania State College of Medicine. Hershey, Pennsylvania. May 2004.
16. "In vivo Mouse Model of Chondrosarcoma Metastasis" [poster presentation] Orthopaedic Research Society. San Francisco, California. March 2004.
17. "An Orthopaedic Surgeon's Experience in Iraq" Annual CME Conference. 5502nd US Army Hospital. Denver, Colorado. March 2004.
18. "A Comparison of the Effects of Intratendinous and Peritendinous Corticosteroid Injections on the Biomechanical Properties of Rabbit Achilles Tendon" American Academy of Orthopaedic Surgeons. San Francisco, California. March 2004.
19. "A Comparison of the Effects of Intratendinous and Peritendinous Corticosteroid Injections on the Biomechanical Properties of Rabbit Achilles Tendon" The Buchanon Lectures. Hershey, Pennsylvania. June 2003.

Innovative Orthopedics

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Board-Certified Orthopedic Surgeon
Orthopedic Tumors/ Osteonecrosiss (AVN)
Joint Transplants
Infections

LEGAL FEE SCHEDULE

Deposition	$1,000.00/hr, 1 hour minimum $4,000.00 per ½ day, $8,000.00 per day
Pre-Deposition/Pre-Trial Conference	$1,000.00/hr, 30 minute minimum
Court Testimony	$10,000 per day, $5,000 per ½ day, half day minimum
Independent Medical Exam (IME)	$675.00 (flat fee)
Medical Record Review:	$600.00/hr, 30 minute minimum
Narrative Report	$100.00 First page $ 75.00 each additional page
Phone Consults	$500.00/hr, 30 minute minimum
*Retainer Required for Medical Record/ Chart Review	$600 pre-payment. Amount will be credited towards medical record review and/or narrative report expense.

LEGAL POLICY INFORMATION

Scheduling Policy	Depositions and Court testimony must be scheduled one month prior to the actual court date/deposition date.
Pre-payment Policy	Payment must be received 14 days prior to the scheduled event.
Cancellation of Deposition Cancellation of Court Testimony	If a cancellation occurs within seven days of the scheduled event, the entire payment is forfeited. Cancellations that are greater than seven days (calendar days) warrant a full refund.
Cancellation Policy-IME	If cancelled within seven days of the IME appt date, $300.00 will be forfeited. Cancellations that are greater than seven days (calendar days) warrant a full refund.

Rates & Terms Administered by Colorado Orthopedic Specialists

Revised 01/2009

January 15, 2010

Julie Mayes Hamrick
HOUSSIERE, DURANT, HOUSSIERE, LLP
1990 Post Oak Boulevard, Suite 800
Houston, TX 77056

Re: Patient: Jose Jimenez

Dear Counsel:

This letter will provide a summary of my expert opinion as related to the complications of total knee arthroplasty experienced by this patient.

1. In forming my opinion, I have reviewed and considered the following, and may use any of the following as an exhibit should my testimony be required at trial:

   Patient's history, operative reports, discharge summaries and chartsticks for primary and revision total knee arthroplasty.

   Office record of patient's treating surgeons.

   Patient's Relevant Radiological and Pathological reports.

   Medical Articles, including:

   Perdue, Koulouvaris, Nestor, & Sculco *The Central Role of Wear Debris in Periprosthetic Osteolysis*, Published online 28 April 2006, Hospital For Special Surgery, NY, NY

   Batista, Ibarra, Ortiz & Melvitz, *Engineering Biomechanics of Knee Replacement*, Applications of Engineering Mechanics in Medicine, May 2004

   Spector, *Biomaterials Survey,* MIT, Harvard Medical School, Brigham & Women's Hospital, VA Boston Healthcare System

2. I am qualified to provide this opinion, as represented by the qualifications presented on my curriculum vitae, attached hereto.A list of all publications which I have authored in the past 10 years is attached to my curriculum vitae.

3. A list of all other cases in which, during the previous four years, I have testified as an expert at trial or by deposition is attached hereto.

4. A copy of my fee schedule, outlining the compensation to be paid for study and testimony in this case is attached hereto.

5. My opinions in this case, based upon my training, knowledge and expertise, along with the basis and reasons for them are as follows:

I am an orthopedic surgeon, with interest and experience in orthopedic implant design. I am a member physician of the Denver Clinic for Extremities at Risk at Preesbyterian/St. Luke's Medical Center in Denver, Colorado. I have not performed any mechanical testing on the device used in this patient. The opinions expressed here are based upon my training, my experience as a practicing orthopedic surgeon, and my knowledge as a result of my regular study of peer-accepted journals and literature, including those listed above which provide specific explanation of my theories, as well as my review of the patient's records.

The common causes of early loosening of implants include mechanical failure (poor initial fit causing micro-motion), poor cement technique (not an issue here), infection, inadequate in-growth surface properties, or (on rare occasion) allergy to metal. When a patient presents with early loosening, and the standard causes of early loosening are ruled out, one could then consider the possibility of osteolysis related to polyethylene debris as a potential cause. Polyethylene wear mediated osteolysis is a well documented major potential long-term complication of total knee arthroplasty. Significant osteolysis is frequently accompanied by loosening.

Osteolysis often results from polyethylene debris particulate in the joint. This debris originates from articulation wear at the implant-polyethylene interface. Osteolysis may be difficult to detect on radiographs or routine surveillance.

Osteolysis occurs when wear debris from a joint prosthesis activates pro-inflammatory signaling, leading to increased osteoclast recruitment and activation. Smaller wear particles are more biologically susceptible to macrophages. Particles taken by macro-inflammatory reaction, if in the vicinity of bone, can cause bone loss, and, subsequently, loosening of the prosthetic device.

Smith and Nephew has trademarked the *Oxinium* technology in prosthetic manufacture. This technology is marketed as "longer lasting" because the patented process of "transforming the surface" of a metal implant to ceramic results in a superior bearing surface, resisting abrasion to minimize generation of polyethylene wear particles.

Strategies to reduce osteolysis by choosing bearing surface materials with reduced polyethylene wear should be balanced by an awareness that reducing the size of wear particles may increase biologic activity, resulting in a more intense inflammatory reaction. Although clinical trials confirm that *Oxinium* technology

results in a lower wear rate, there is no clinical data which indicates that the technology will reduce osteolysis.

At a molecular level, wear particles generated by range of motion in a knee prosthesis activate MAP kinase cascades, NfkB proteins and other transcription factors, and induce expression of suppressors of cytokine signaling. To explain, the body's mechanism of defense against foreign particles is the macrophage, a cell which becomes actively mobile when stimulated by inflammation in the body. When a macrophage attacks a particle which it cannot degrade, it mounts a pro-inflammatory response, producing cytokines, which initiate recruitment and activation of osteoclasts. These activated osteoclasts are responsible for the pathological bone destruction in polyethylene mediated osteolysis…which in turn, can cause implant loosening.

Mr. Jimenez' record indicates no infection of his Profix implant. Pre-operative X-rays reportedly indicated osteolysis involving the tibial component.

The opinion presented herein may be supported with other evidence determined throughout the discovery process at a later date in this case. If testing of the subject device is an option, it may be possible to further explain the physiology of the loosening. However, based upon the facts presented above, it is my expert opinion that it is possible that this patient suffered loosening of his arthroplasty component as a result of a defect in the design or manufacturing of the product used.

Sincerely,

1-15-10

Ronald Hugate, MD